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10/594,918	09/29/2006	Yoshinori Abe	4633-0189PUS1	5532

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EXAMINER	
GUGLIOTTA, NICOLE T	
ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
10/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,918	ABE ET AL.	
	Examiner	Art Unit	
	NICOLE T. GUGLIOTTA	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 - 5, 8 - 10, 12 - 15, 24 - 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 - 5, 8 - 10, 12 - 15, 24 -27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/9/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner's Note

1. Examiner acknowledges the cancellation of claims 1, 6, 7, 11 and 16 - 23, and the addition of claims 24 - 27.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. At paragraph [0023] and [0024], Applicant explains that "graft polymerization" takes place between the biocompatible component and some sort of activated DLC surface or an intermediate layer-coated DLC surface. Both the specification and the remarks filed 7/2/08 state that the attachment of the biocompatible component cannot take place otherwise. Independent claim 2 lacks a recitation of the activated surface or intermediate layer.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 24 – 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 24 can be interpreted as (1) sugar being directly bonded to the DLC surface (as part of the polymer linker), or as (2) the sugar being the biocompatible component, which is indirectly bonded to the DLC surface via a polymer linker. Claims 25 – 26 are dependent upon claim 24 and therefore are also rejected to.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 2, 3, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanga et al. (U.S. Patent No. 6,607,908 B1), as evidenced by Handbook of Physical Vapor Deposition (PVD) Processing, pg 539.

8. In regard to claims 2 and 3, Tanga et al. disclose a diamond circular plate including non-diamond carbon: a peak ratio of non-diamond carbon

(uncompleted diamond) with respect to diamond carbon (completed diamond) (Col. 3, Lines 24 – 29). In addition, Tanga et al. disclose a support with carbons exposed on the surface (corresponds to applicant's "diamond-like carbon film") The surface is chemically modified with a hydroxyl group, a carboxyl group (Col. 1, Lines 58 - 63). The carboxyl group or hydroxyl group is bonded to a surface of the support through a peptide or ester linkage (corresponds to applicant's graft polymerization) and so on and DNA (corresponds to applicant's "biocompatible component") and so on can be immobilized easily (Col. 1, Lines 58 - 63).

9. The Handbook of PVD Processing discloses the definition of "diamond-like carbon (DLC) to be "an amorphous carbon material with mostly sp^3 bonding that exhibitis many of the desirable properties of the diamond material" (Page 539, Section 9.7.8).

10. The "diamond circular plate including non-diamond carbon" disclosed by Tanga et al. contains amorphous carbon material and contains sp^3 bonding symmetry, due to mixture of ratio of complete and incomplete diamond. Therefore the Examiner considers the material used by Tanga et al to be DLC.

11. In regard to claims 2 - 4, Examiner interprets these as product-by-process claims. Therefore these claims are not dependent upon the process of graft polymerization. Graft polymerization will not result in a different structure than suggested by the prior art discussed below (see paragraphs 15 and 16 of this office action).

12. Examiner refers applicant to MPEP § 2113 [R - 1] regarding product-by-process claims. "The patentability of a product does not depend on its method or production. If the product in the product-by-process claim is the same as or obvious from a product or the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777, F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citation omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218, USPQ 289, 292 (Fed. Cir. 1983)

13. Claim 2, 3, 8, and 12 - 15 rejected under 35 U.S.C. 102(b) as being anticipated by Steffen et al. (*Surf. Interface Anal.* **29**, 386 – 391 (2000); submitted by applicant).

14. In regard to claim 2, Steffen et al. disclose a diamond-like carbon (DLC) film system that consists of a chemically inert, uniform, dense and highly tetrahedrally bonded, hydrogenated amorphous carbon film (ta-C:H) with high adherence to the substrate and bioactive heparin macromolecules that are covalently bonded to the ta-C:H film surface (Figure 1 & Page 387, 2nd Col., 2nd paragraph).

15. In regard to claim 3, Steffen et al. disclose heparin to be a polymer, where n – 7 – 10 (Figure 1). Schwarz et al. disclose grafting processes can be used to coat or modify the surface of the medical device or a part of the medical device with the following materials: fluorine-based monomers (hydrofluorocarbons), one or more monomers used alone or in combination in order to form blends, cross-linked polymers, copolymers and interpenetrating network of polymers (Column 11, Lines 3 – 15).

16. In regard to claim 8, Steffen et al. disclose the bioactive heparin macromolecules (Figure 1) to have a carboxyl group (COO^-), an amino group (-NH-), and a hydroxy group (-OH). In addition to an amine group ($-NH_2$) bonded to the DLC film surface.

17. In regard to claim 12, Steffen et al. disclose the substrate materials (base materials) were PTFE vascular prostheses, PTFE and polystyrene films, as well as Si(100) wafers (Page 388, Col. 1, first paragraph of the experimental section).

1. In regard to claims 13, 14, and 15, Steffen et al. disclose the film and surface-immobilized bioactive molecules to optimize haemocompatibility for artificial implants of the cardiovascular system (Abstract and Page 386, Col.1, paragraph 1). In addition, the use of DLC films on polymers give rise to a universal application of these carbon materials for medical devices, such as total

joint replacements, heart valves, catheters, stents, intravascular insertion devices and more (Page 388, Col. 1, first paragraph).

2. In regard to claims 24 and 25, Steffen et al. disclose the DLC film surface were exposed to an ammonia plasma to functionalize efficiently the surface with reactive amino groups. The desired formation of primary amines proves the binding sites for the heparin (Page 388, Col. 1, 2nd paragraph). Examiner notes that while heparin is a sugar-based molecule, the heparin is the "biocompatible component", not the "chain" connecting the biocomponent to the DLC. The "chain" connecting to the DLC is the amino group groups the DLC was modified with.

3. In regard to claims 26 and 27, Steffen et al. disclose the DLC film surface were exposed to an ammonia plasma to functionalize efficiently the surface with reactive amino groups. The desired formation of primary amines proves the binding sites for the heparin (Page 388, Col. 1, 2nd paragraph). Examiner notes that while heparin is a sugar-based molecule, the heparin is the "biocompatible component", not the "chain" connecting the biocomponent to the DLC. The "chain" connecting to the DLC is the amino group groups the DLC was modified with. In regard to ionic bonding, Steffen disclose a prior reference, "Hollohan", discloses results of plasma treatment *promoted ionic heparin binding* between its negatively charged sulphate ester groups and the quaternary ammonium sites of

the alkylated samples (Page 388, Col. 2, second paragraph of results and discussion section).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 3 – 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steffen et al., in view of Palmaz et al. (U.S. Patent No. 6,537,310 B1)

6. Steffen et al. disclose a biocompatible layer (heparin) attached to a diamond-like carbon (DLC) layer, which is applied to a substrate (base material). However, Steffen et al. do not disclose the biocompatible layer to contain silicon of vinylmonomers containing fluorine.

7. Palmaz et al. disclose the numerous attempts to increase endothelialization of implanted stents, including imparting a diamond-like carbon coating onto the stent (U.S. Pat. No. 5,725,573), coating the stent, under ultrasonic conditions, with a synthetic or biological, active or inactive agent, such as heparin, endothelium derived growth factor, vascular growth factors, *silicone*, polyurethane, or *polytetrafluoroethylene* (U.S. Pat. No. 5,891,507), coating a

stent with a silane compound with vinyl functionality, then forming a graft polymer by polymerization with the vinyl groups of the silane compound (U.S. Patent No. 5,782,908), grafting monomers, oligomers or polymers onto the surface of the stent using infrared radiation, microwave radiation or high voltage polymerization to impart the property of the monomer, oligomer or polymer to the stent (U.S. Pat. No. 5,932,299).

8. It would have been obvious to one skilled in the art at the time the invention was made to graft biocompatible layers containing silicon and/or a vinylfluoride monomer molecules (such as silicon and polytetrafluoroethylene) because such components and methods are commonly found in the art for increasing endothelialization and antithrombogenicity, as taught by Palmaz et al. This is further supported by Kiezulas (U.S. Patent No. 5,026,607), Schwarz et al. (U.S. Patent No. 6,368,658 B1), Sasaki et al. (U.S. Patent No. 5,489,303), David (U.S. Patent No. 6,197,120 B1), Bray et al. (U.S. Patent No. 6,468,642 B1) and Veerasamy et al. (US 2001/0044030 A1).

9. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steffen et al., in view of Lemelson et al. (U.S. Patent No. 6,083,570).

10. Steffen et al. disclose a biocompatible layer attached to a diamond-like carbon (DLC) layer, which is applied to a substrate (base material). However,

Steffen et al. do not disclose the use of an intermediate film between the DLC and the substrate (base material).

11. Lemelson et al. disclose articles with synthetic diamond or diamond-like carbon coatings with an intermediate amorphous metal bonding later. The residual stress in diamond and diamond-like thin film coatings applied to metal, cermet and ceramic substrates can be reduced to acceptably low levels by using an intermediate film coating of amorphous ("glassy") metal (Column 3, Lines 54 - 65). Such articles include dental tools and medical prostheses or implants intended for long-term use inside the human body (Column 4, Lines 4 – 11). The intermediate layer may be comprised of carbides or silicon. SiC is most preferred (Column 4, Lines 33 - 38).

12. It would have been obvious to one skilled in the art of diamond-like carbon films at the time the invention that the addition of an intermediate SiC layer between the DLC would help to reduce the residual stress in diamond-like carbon thin film coatings used for medical applications. An organosilicon intermediate layer for increased adherence between a substrate and a DLC is also disclosed by Kato et al. (U.S. 5,763,072).

Response to Arguments

18. Applicant argues they have established their product cannot be made by any other process than graft polymerization. They argue the covalent bonding

disclosed by Steffon would be impossible to modify with a biocompatible component due to the smooth, inert surface (Remarks, Page 7, last paragraph).

19. Applicant's arguments filed 7/2/2008 have been fully considered but they are not persuasive. Steffen et al. disclose the DLC film surface were exposed to an ammonia plasma to functionalize efficiently the surface with reactive amino groups. The desired formation of primary amines proves the binding sites for the heparin (Page 388, Col. 1, 2nd paragraph). Examiner maintains the product-by-process limitations of claims 2 – 4 because not only does Steffen et al. disclose a process other than graft polymerization in which to attach a biomolecule to a DLC surface, Steffen et al. also disclose how they modified the DLC surface by amination to make it reactive for biomolecular attachment. Clearly it is not impossible to introduce a biocompatible component to a surface of a DLC film by a different method, as applicant claims.

20. Applicant argues "the various grafting procedures disclosed by Palmaz do not graft any of the components onto an inert and smooth material, such as diamond-like carbon film. Stents are generally made of steel" (Remarks, Page 8 2nd paragraph).

21. Applicant's arguments with respect to claims 2 and 3 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE T. GUGLIOTTA whose telephone number is (571)270-1552. The examiner can normally be reached on M - Th 8:30 - 6 p.m., & every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on 571-272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NICOLE T. GUGLIOTTA
Examiner
Art Unit 1794

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